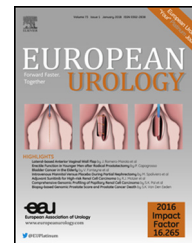


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Financial Conflicts of Interest Among Authors of Urology Clinical Practice Guidelines

Austin Carlisle^a, Aaron Bowers^{b,*}, Cole Wayant^b, Chase Meyer^b, Matt Vassar^b

^a Department of Surgery, Oklahoma State University Medical Center, Tulsa, Oklahoma, USA; ^b Oklahoma State University Center for Health Sciences, Tulsa, Oklahoma, USA

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Abstract

Background: Recent studies have highlighted the presence of disclosed and undisclosed financial conflicts of interest among authors of clinical practice guidelines.

Objective: We sought to determine to what extent urology guideline authors receive and report industry payments in accordance with the Physician Payment Sunshine Act.

Design, setting, and participants: We selected the 13 urology guidelines that were published by the American Urological Association (AUA) after disclosure was mandated by the Physician Payment Sunshine Act. Payments received by guideline authors were searched independently by two investigators using the Open Payments database.

Outcome measures and statistical analysis: Our primary outcome measure was the number of authors receiving payments from industry, stratified by amount thresholds. Our secondary outcome measure was the number of authors with accurate conflict of interest disclosure statements.

Results and limitations: We identified a total of 54 author disclosures. Thirty-two authors (59.3%) received at least one payment from industry. Twenty (37.0%) received >\$10 000 and six (11.1%) received >\$50 000. Median total payments were \$578 (interquartile range \$0–19 228). Twenty (37.0%) disclosure statements were inaccurate. Via Dollars for Docs, we identified \$74 195.13 paid for drugs and devices directly related to guideline recommendations. We were limited in our ability to determine when authors began working on guideline panels, as this information was not provided, and by the lack of specificity in Dollars for Docs.

Conclusions: Many of the AUA guideline authors received payments from industry, some in excess of \$50 000. A significant portion of disclosure statements were inaccurate, indicating a need for more stringent enforcement of the AUA disclosure policy.

Patient summary: Pharmaceutical company payments to doctors have been shown to influence how doctors treat patients. If these doctors are charged with making clinical recommendations to other doctors, in the form of clinical practice guidelines, the issue of industry payments becomes more severe. We found that many urologists on guideline panels receive money from industry and that a significant portion did not disclose all payments received.

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* Corresponding author. Oklahoma State University Center for Health Sciences, 1111 W 17th St., Tulsa, OK 74107, USA. Tel. +1 801 808 0187.

E-mail address: Aaron.Bowers@okstate.edu (A. Bowers).

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1. Introduction

Clinical practice guidelines (CPGs) are widely used by clinicians to inform patient care decisions. They are derived by a systematic review of evidence leading to a set of recommendations intended to optimize patient care. The Institute of Medicine states that for CPGs to be trustworthy and reliable, they should be transparent to minimize bias, conflicts of interest (COIs), and distortion [1]. When considering the widespread use of CPGs in the patient care setting, physicians would do well to consider COIs that could affect the guideline recommendations. For example, a systematic review found a positive correlation between industry-funded studies and/or author COIs and results favoring the sponsor in 23 of 26 included studies [2]. Campsall et al [3] examined 95 national and international organizations that produced 290 CPGs during 2012, finding that 63% of these organizations reported receiving funds from a biomedical company.

In 2012, Norris et al [4] found that only 46% of organizations producing CPGs had a COI policy. A later study found that of the organizations with a COI policy, only 42% made disclosure statements publicly available [5]. In 2013, the Physician Payments Sunshine Provision of the Affordable Care Act was passed, which mandated that manufacturers of drugs, devices, and other medical supplies covered by Medicare, Medicaid, and Children's Health Insurance Program had to report specific payments to physicians or medical teaching institutions. This act also required these manufacturers to report ownership or investment interests [6]. This information is available for review on a public website (known as Open Payments) in an attempt to provide transparency regarding the nature of industry payments issued to physicians [7].

Recent studies have examined the Open Payments database in relation to CPG panelists and found concerning results. A study on COIs for CPGs produced by the American Academy of Neurology found that COIs were common: 46 of the 50 guidelines included for review had at least one conflicted author [8]. Checketts et al [9] found that among 49 authors of dermatology guidelines from 2013 to 2015, each author received a mean financial payment of \$157 177 and 22 authors did not accurately disclose COIs. In a similar study of otolaryngology guidelines, Horn et al [10] found that authors received a mean payment of \$18 431 from 2013 to 2015. The extent and nature of industry payments to urology CPG panelists remain unknown and represent a knowledge gap that needs to be filled. Here, we apply a methodology similar to that used by Checketts et al [9] and Horn et al [10], and evaluate payments made to panel members of CPGs published by the American Urological Association (AUA), compare COI disclosures to Open Payments data to determine accuracy, and evaluate to what degree the AUA adhered to its disclosure policy during the production of its guidelines.

2. Patients and methods

We searched for CPGs in November 2017 using the AUA website. For our study, AUA guidelines had to be published between 2014 and 2016, and

contain COI disclosures. The time frame of 2014 to 2016 was used because 2013 was the 1st year that industry payment data were made publicly available, with 2016 data being most recent. The AUA requires interests within 12 mo prior to assuming a role with the AUA [11]. We were unable to determine the date that each author assumed a panel member role with the AUA, and AUA guidelines have been shown to take many years to develop [12]. The only dates available within the CPGs where we could prove authors were the date of Board of Director approval and the final date parameter for the literature search. As a proxy for the date, an author assumed an AUA panel member role, and to avoid miscalculations and misattribution of payments to authors, we used 12 mo prior to the final date parameter of the literature search as the first date a panel member must be conflict free and 1 mo prior to guideline approval as the conclusion of their conflict-free interval. We stopped 1 mo prior to approval because each guideline undergoes peer review. Figure 1 provides an overview of the CPG development process and highlights the conservative nature of the dates we included in our analysis.

Physician names were extracted from guidelines and entered into the Open Payments search tool. In the event of duplicate search results, middle names, medical specialty, and location were used to identify the correct individual. If physicians could not be located after multiple searches, they were considered to have received \$0 in industry payments.

Author name, COI disclosure information, and payment data were collected. COI disclosures were extracted directly from the guidelines. The data were then reviewed for accuracy by A.B. by searching each physician a second time and verifying payment information.

Open Payments data are divided into four sections [13]:

1. *General payments*: broad category including consultant fees, travel and lodging, honoraria, education, food/beverage, and more
2. *Research payments*: research projects where the physician is not the principal investigator
3. *Associated research payments*: research projects where the physician is the principal investigator
4. *Ownership*: both the amount invested in a company and interest paid to the physician

All calculations were done by A.B. and C.W. using Microsoft Excel. Author names and the disclosed COI information, including the company's or organization's name and type of COI, were extracted by A.C., A.B., C.W., and M.V. Food and beverage payments were removed from all analyses.

We evaluated whether the companies, from which guideline authors received payments, manufactured products related to the guideline topics. To do so, we searched the ProPublica website Dollars for Docs [14] for each author to identify whether payments were made for the research, development, or consultation for specific drugs, devices, or equipment involved in the guideline for which they were a panel member.

3. Results

Six guidelines from the AUA were identified. We excluded the cryptorchidism guideline because the authors did not recommend any drugs or devices, rendering us incapable of deeming any payment as a COI. Ten authors were not physicians, and four authors were found to be based in Canada. These 14 authors were excluded, and 54 authors remained for our investigation.

While serving on the AUA guideline panels, 32 authors (59.3%) received at least one payment from industry.

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