Transparency of industry payments needed in clinical practice guidelines

Matt Vassar, Michael Bibens, Cole Wayant

10.1136/bmjebm-2018-111020

Oklahoma State University Center for Health Sciences, Tulsa, Oklahoma, USA

Correspondence to:
Dr Matt Vassar, Oklahoma State University Center for Health Sciences, Tulsa, OK 74107, USA; matt.vassar@okstate.edu

To cite: Vassar M, Bibens M, Wayant C. *BMJ Evidence-Based Medicine* 2019;**24**:8–9.

The Evidence-Based Medicine Manifesto[1] outlines steps to develop more trustworthy evidence. These steps include reducing conflicts of interest and producing better, more usable clinical practice guidelines. Here, we argue that self-disclosure of industry payments by guideline panellists is inadequate and often inaccurate. The international community should come together to require open and transparent reporting of all industry payments made to physicians by drug and device companies. Such an initiative would accomplish many things, including better policies and verification of conflicts of interests for guideline panel members.

In the USA, the Open Payments Program—established as part of the Affordable Care Act—catalogues payments made to physicians by pharmaceutical and device companies and classifies payments by type. General payments include consulting fees, honoraria, gifts, food and beverage, and travel; research payments include funds received for basic and applied research or product development; associated research payments include research funding for which the physician was a principal investigator; and ownership includes investment interests in companies. Since the creation of this programme, numerous studies have evaluated the extent of industry relationships across most medical specialties. In general, findings from these studies suggest that payments are prevalent. Between 31 August and 31 December 2016 alone, physicians received 4.4 million payments, totalling US$2.6 billion.[2]

The transparency created as a result of the Open Payments Program prompted investigations into payments received by medical journal editors[3] and researchers.[4 5] We have recently conducted investigations to examine the extent of industry payments made to clinical practice guideline panel members and whether the panellists' disclosure statements listed in these guidelines match the payments catalogued on the Open Payments Database.[6–9] In some cases, the database lists the specific product or category for which panellists received payments, and these entries make it possible to examine whether panel members received payments from companies that manufacture products relevant to guideline topics.

This trend towards transparent reporting of industry payments can be found worldwide. Among the 35 countries comprising the Organisation for Economic Cooperation and Development, 7 have adopted statutory disclosure regulations.[10] The Bertrand Law in France and the 18th edition of the Medicines Australia Code of Conduct are country-specific examples. More broadly, the disclosure requirement by the European Federation of Pharmaceutical Industries and Associations (EFPIA) dictates that all 33 national industry associations that are members of the EFPIA have disclosure policies; however, compliance for most countries is not mandatory and, in some instances, such policies may conflict with national laws. Fabbri *et al*[11] recently evaluated 10 disclosure policies from 9 countries within the EFPIA and found substantial variation between countries—most notably between governmental and self-regulatory approaches—regarding the comprehensiveness of data, completeness of reporting, opt-out availability and payment categories (food and gifts were not always required). Further, data format differed, with some countries providing only PDF versions. The substantial limitations of the current models would require careful attention and would pose many challenges for the EFPIA to develop a centralised database for use in tracking industry payments. The voluntary nature of payment disclosure limits the utility of these data, and investigations of physician–industry relationships cannot adequately be conducted.

Thus, to make industry payments transparent worldwide would require the commitment of governments to enact sunshine legislation and the proper standardisation of data elements to make these data useful. To make passing legislation more feasible, these governments may operate alone or as a group to enact legislation based on a common framework. Industry payment data should be made publicly available, searchable and analysable. Common data elements have been established for clinical trial registries worldwide by the WHO,[12] suggesting that it is feasible for international implementation of financial disclosure policies. And while certain data elements—such as pharmaceutical or device company, amount of payment, and reason for payment—are essential, allowing each country the freedom with other elements may promote the feasibility of enacting legislation. The creation of payment databases would accomplish many things, one of which would be to create a data source to understand the extent of conflicts among clinicians serving in positions—like clinical practice guideline panels—where decision making requires objectivity free from the bias of industry influence.

Contributors All authors contributed equally to the conception and writing of this manuscript.

Competing interests None declared.

Patient consent Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

References

1. **Evidence Live**. Manifesto. http://evidencelive.org/manifesto/ (accessed May 2018).
2. **Marshall DC**, Jackson ME, Hattangadi-Gluth JA. Disclosure of industry payments to physicians: an epidemiologic analysis of early data from the open payments program. *Mayo Clin Proc* 2016;**91**:84–96.
3. **Liu JJ**, Bell CM, Matelski JJ, *et al*. Payments by US pharmaceutical and medical device manufacturers to US medical journal editors: retrospective observational study. *BMJ* 2017;**359**:j4619.
4. **Hannon CP**, Chalmers PN, Carpiniello MF, *et al*. Inconsistencies between physician-reported disclosures at the AAOS Annual Meeting and industry-reported financial disclosures in the open payments database. *J Bone Joint Surg Am* 2016;**98**:e90.
5. **Thompson JC**, Volpe KA, Bridgewater LK, *et al*. Sunshine act: shedding light on inaccurate disclosures at a gynecologic annual meeting. *Am J Obstet Gynecol* 2016;**215**:661.e1–7.
6. **Checketts JX**, Cook C, Vassar M. An evaluation of industry relationships among contributors to AAOS Clinical practice guidelines and appropriate use criteria. *J Bone Joint Surg Am* 2018;**100**:e10.
7. **Checketts JX**, Sims MT, Vassar M. Evaluating industry payments among dermatology clinical practice guidelines authors. *JAMA Dermatol* 2017;**153**:1229–35.
8. **Horn J**, Checketts JX, Jawhar O, *et al*. Evaluation of industry relationships among authors of otolaryngology clinical practice guidelines. *JAMA Otolaryngol Head Neck Surg* 2018;**144**:194–201.
9. **Carlisle A**, Bowers A, Wayant C, *et al*. Financial conflicts of interest among authors of urology clinical practice guidelines. *Eur Urol* 2018 [Epub ahead of print 7 May 2018].
10. **Grundy Q**, Habibi R, Shnier A, *et al*. Decoding disclosure: comparing conflict of interest policy among the United States, France, and Australia. *Health Policy* 2018;**122**:509–18.
11. **Fabbri A**, Santos A, Mezinska S, *et al*. Sunshine policies and murky shadows in europe: disclosure of pharmaceutical industry payments to health professionals in Nine European Countries. *Int J Health Policy Manag* 2018;**7**:504–9.
12. **WHO**. WHO Data Set. 2017. http://www.who.int/ictrp/network/trds/en/ (accessed May 2018).