

Real Transparency in Medicine: Time to Act

Clifford A. Hudis, MD¹, and Robert W. Carlson, MD ²

The growing complexity of medical science in general (and oncology in particular), along with greater disease specialization, increased time pressure on clinicians, and the accelerating rate of scientific advancement, among many other factors, motivates practitioners and payers to turn to vetted, evidence-based resources to efficiently identify the most appropriate management options for individual patients and groups. Clinical practice guidelines, as published by both of our organizations, are a component of this ecosystem, but there are others, including pathways, quality and outcome measures, and other types of educational materials.¹ Across this spectrum of resources, users expect to receive unbiased, well-supported, transparent, up-to-date guidance for the clinical challenges that they face. Among many other contributors to this effort, clinical experts help to weigh evidence and provide scientific interpretation and to provide context and a reality check for specific recommendations.

It has long been understood and recognized that medical experts are often engaged with health care entities in ways that can lead to potential conflicts of interest in a number of domains, including the development of clinical recommendations.² However, there is arguably a range of engagements that are necessary and beneficial in terms of advancing scientific progress for the good of society even if there are other less useful relationships.

The specific rules and limits concerning potential conflicts of interest vary widely from organization to organization and are, for the moment, a matter for society as a whole or for individual institutions to define and regulate. That is not our focus in this editorial. Instead, we address a crucial first step in managing potential conflicts of interest, and that is transparency. To be certain, both the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN) care very deeply about the integrity of medical science, and disclosure is the best method that we have for identifying conflicts of interest. Simply put, we believe that any relationships with health care entities that could give rise to a financial conflict of interest need to be transparently disclosed.³ This is “universal” or “general” disclosure, as opposed to “relevant” or “specific” disclosure. The historically used but inconsistently defined standard of “relevance” puts an assessment responsibility on the discloser or on the editors and peer reviewers. It can be a bit like asking the proverbial fox to guard the chicken coop and can only raise concerns when readers discover an engagement that they believe to be relevant despite the authors’ or editors’ and publishers’ assessment otherwise. Using relevance as a standard virtually ensures allegations of incomplete disclosure at some point. This risks reputational harm to the entire profession, consumes time and effort by institutions and individuals, and removes the ability of guideline developers such as our organizations to consistently apply conflict management strategies. A universal disclosure standard addresses this issue by eliminating any excuse that an engagement was unrelated to the matter at hand because that latter assessment would no longer matter.

Relevance versus universal disclosure is only one example of the many challenges that we face today. In other ways, the medical profession has watched as a collection of disjointed disclosure systems evolved into traps for the unwary, the busy, and the well-meaning participant in almost all aspects of publishing, clinical practice guideline development, and education. We do not have a functional system per se. Instead, we find ourselves with a number of purpose-built systems that ask individuals to repeatedly report different information about different entities at different times covering different backward-looking time periods, and we make these data inconsistently available for review on uncoordinated schedules and in different formats. A recent internal review by ASCO found that the vast majority of authors who published in the *Journal of Clinical Oncology* over a fixed period of months had self-disclosed information that was discordant with what was subsequently reported (note “subsequently,” not concurrently, available) by companies in Open Payments for a similar time period (Liz Garrett-Mayer, PhD, February 12, 2019, unpublished data). Interestingly, the overreporting and underreporting

Corresponding author: Robert W. Carlson, MD, National Comprehensive Cancer Network, 3025 Chemical Road, Suite 100, Plymouth Meeting, PA 19462; carlson@nccn.org

¹American Society of Clinical Oncology, Alexandria, Virginia; ²National Comprehensive Cancer Network, Plymouth Meeting, Pennsylvania

See referenced original article on pages 4069-75, this issue.

DOI: 10.1002/cncr.32407, **Received:** June 20, 2019; **Revised:** June 24, 2019; **Accepted:** June 25, 2019, **Published online** July 29, 2019 in Wiley Online Library (wileyonlinelibrary.com)

could be found in both directions (author disclosures not in Open Payments and vice versa). Asking different questions, that is, using different systems, different definitions, different disclosers, and different time periods, naturally results in inconsistent and discordant answers. However, the sheer volume of discordance overall—the fact that discordance is the rule, not the exception—suggests that it is not individuals who are failing but rather the “system” as a whole.

Compounding this structural defect is the willingness of too many to assume that Open Payments represents the “truth.”⁴ This is wrong. For example, an annual analysis conducted internally by NCCN finds that the majority of NCCN guideline panel members have general or research conflicts of interest reported in Open Payments, and 0.5% to 1.2% are disqualified because they exceed the NCCN’s published thresholds of financial conflict. However, this annual exercise also finds that Open Payments data are inaccurate or misleading approximately 50% of the time when financial payments as reported appear to exceed NCCN-defined thresholds when in fact they do not (Kristina Gregory, RN, MSN, June 19, 2019, unpublished data), and any apparent disqualification, therefore, requires verification with the panel member before any action is taken.

Why is Open Payments flawed? The content is uploaded only by companies with marketed products covered by federal programs in the United States, and it reports only transfers of value to licensed physicians (eventually to be expanded). Examples of missed potential conflicts of interest include equity holdings and patents for premarket products as well as spousal/domestic partner/dependent employment or holdings. Personally, we have had to spend hours correcting minor and major errors in the database, and this is not something that all busy clinicians have the time, resources, and patience to do. Hence, errors live on unchallenged, and the act of “verifying” author self-disclosures against Open Payments both overvalues the federal database and ironically may undercut transparency by missing types of potential conflicts that are not captured there.

In this issue of *Cancer*, Saleh et al⁵ report that a relatively small number of guideline authors had financial relationships reported in Open Payments that either were not responsive to ASCO’s disclosure questions or were not disclosed to ASCO. Similar findings have been published about NCCN guidelines.⁶ Compliance is a serious issue, and our intent is not to minimize the seriousness of underdisclosure or nondisclosure. However, we also do not believe that these instances necessarily represent malintent or malfeasance on the

part of individual authors or a lack of diligence by the involved institutions (including our own employers). Instead, this represents one more in a potentially endless number of illustrative specific examples of all that is wrong—and must be fixed—with disclosure as currently practiced in the United States.

Believing that the vast majority of our colleagues want to do the right thing and aiming to support them (rather than focusing on the small number who might purposefully underreport and who might attempt to circumvent any system), we argue that it is our collective responsibility to improve the system. To that end, we identify 3 specific current challenges followed by potential solutions. The challenges are as follows:

1. Health care providers and experts (“covered individuals”) may be engaged with health care entities in a number of ways, including the conduct of research, consultancies, educational services, and more. The rules for disclosing such engagement are not standard and are currently determined institutionally. Standard and consistent terminology is required.
2. Although rules about allowable engagements will vary by institution and activity, this becomes critical in the development of clinical practice guidelines. It should be easy for covered individuals to be fully transparent (and difficult not to be transparent) about such engagements so that potential conflicts of interest can be identified and managed. At present, multiple entities, institutions, and publishers collect disclosures in customized ways that are inconsistent and incompatible with one another and that are time-consuming for covered individuals to complete.
3. Health care entities report into Open Payments after a significant delay and in isolation from the physicians with whom they engage.

The proposed solutions are as follows:

1. Definitions of *research funding*, *consultancy*, *honoraria*, *travel support*, and so forth should be standardized and applied consistently.
 - a. We need one definition for *consulting*, one for *honoraria*, and so on.
 - b. Definitions and reporting of equity and intellectual property interests should be standardized.
 - c. The reportability of indirect payments (from companies to an intermediary or from companies to the researcher’s institution) should be resolved and standardized.

- d. Reporting of relationships with precommercial companies should be addressed and standardized.
 - e. The reportability of family member relationships and uncompensated relationships should be resolved and standardized.
2. There should be one source of universal disclosure. The house of medicine (not oncology specifically) should provide a simple, easy-to-use, easily vetted, shared, and accessible resource so that covered individuals can easily document, confirm, and share all of their potential conflicts. A uniform database should exist, and each clinician should have access to a shareable URL that provides current and prior (date-stamped) reports that are accepted by all journals, meetings, guideline groups, and institutions.
 3. Companies that are subject to sunshine reporting should also be required to notify covered individuals, in nearly real time, when and what they are reporting so that there is no disconnect or time lag.

Only after these solutions have been implemented and all authors confront the “clear and concise reporting standards” recommended by Saleh et al⁵ can we have confidence that we can accurately verify self-reported conflicts of interest in guideline development. Attempts at verification within the current broken, disconnected, uncoordinated system will simply continue to potentially malign the large majority of well-meaning participants because it will assuredly continue to identify nonconcordance due to true or false underreporting while still missing substantial potential conflicts. Verification under the proposed new system would be simple, cost-effective, and meaningful.

Saleh et al⁵ have added one more observation to a string of inevitable observations allowing us to conclude that the current disclosure nonsystem is no system at all. Well-meaning individuals, who are often volunteering

their time and expertise to help fellow clinicians deliver evidence-based care to their patients, face obstacles because nearly every component of the current disclosure milieu has evolved in ways that increase the risk of omission. Disclosure is too central to the credibility of medical science for us to allow this dysfunction to continue. We as a community have to do better, and this is a call to action to advocate for and insist on an upgraded and simplified disclosure environment so that our colleagues can volunteer, contribute, write, and continue to guide us without fear of a “gotcha” as their reward.

FUNDING SUPPORT

No specific funding was disclosed.

CONFLICT OF INTEREST DISCLOSURES

Clifford A. Hudis is employed by the American Society of Clinical Oncology (see also <https://coi.asco.org/share/FW3-5YRW/CliffordHudis>). Robert W. Carlson is employed by the National Comprehensive Cancer Network and reports being issued US patent D848,448S for Evidence Blocks (part of National Comprehensive Cancer Network guidelines).

REFERENCES

1. Graham R, Mancher M, Wolman DM, Greenfield S, Steinberg E, eds. *Clinical Practice Guidelines We Can Trust*. Washington, DC: National Academies Press; 2011.
2. Relman AS. Dealing with conflicts of interest. *N Engl J Med*. 1984;310:1182-1183. doi:10.1056/NEJM198405033101809
3. Council of Medical Specialty Societies. Code for interactions with companies. <https://cmss.org/wp-content/uploads/2016/02/CMSS-Code-for-Interactions-with-Companies-Approved-Revised-Version-4.13.15-with-Annotations.pdf>. Published April 2015. Accessed June 20, 2019.
4. Khan R, Scaffidi MA, Rumman A, Grindal AW, Plener IS, Grover SC. Prevalence of financial conflicts of interest among authors of clinical guidelines related to high-revenue medications. *JAMA Intern Med*. 2018;178:1712-1715. doi:10.1001/jamainternmed.2018.5106
5. Saleh RR, Majeed H, Tibau A, Booth CM, Amir E. Undisclosed financial conflicts of interest among authors of American Society of Clinical Oncology clinical practice guidelines. *Cancer*. 2019;125:4069-4075.
6. Mitchell AP, Basch EM, Dusetzina SB. Financial relationships with industry among National Comprehensive Cancer Network guideline authors. *JAMA Oncol*. 2016;2:1628-1631. doi:10.1001/jamaoncol.2016.2710