RESEARCH LETTER

Effect of the American Society of Clinical Oncology’s Conflict of Interest Policy on Information Overload

More information than can be managed in the time allotted is considered information overload.1 Prior evidence suggests that average reading comprehension in English is 228 words per minute (3.8 words per second).2 Proofreading can be performed at approximately 200 words per minute (3.3 words per second).3 When a large volume of text is presented for a short period at which readers have to exceed these speeds, the ability of readers to comprehend is in doubt.

The American Society of Clinical Oncology (ASCO) mandates the disclosure of financial conflict of interest (COI) in a slide at the start of oral presentations at their annual meeting. Between the 2014 and 2015 meetings, the COI policy changed, asking speakers to disclose not only relevant financial conflicts but also any financial relationships (deemed relevant or not).4 We sought to examine whether this policy change is associated with increased information overload in COI slides.

Methods | We examined videos of presentations from 2014 to 2015 from the ASCO virtual meeting library (http://meetinglibrary.asco.org/), a database of ASCO annual meetings, organized by track—1 of 15 to 30 themes, such as breast cancer, lung cancer, or tumor biology. Within each track, educational sessions pertain to updates in management or care, whereas oral sessions present original research.

We noted the duration the COI slide was visible and the number of COI disclosure slides for up to 5 presentations in the oral and educational sessions for each track. Videos were not screened before inclusion. Welcome presentations were excluded.

We used the video player time stamp for timing. Time was noted when the standard ASCO COI disclosure slide was displayed and stopped. Some slides had a fade-out transition, and time was noted when the content was no longer clearly visible. Nonstandard disclosure slides were excluded.

Word count was based on Microsoft Word’s count function. The title of the disclosure slide and standard text were excluded.

Descriptive statistics were performed using STATA statistical software, version 12.0 (StataCorp), and R, version 3.2.2. The comparison test was the Wilcoxon rank sum test. Four words per second was set as the threshold for information overload to provide a generous estimate. This investigation of meeting presentations was exempt from institutional review board approval.

Results | We examined 469 presentations given by 458 speakers. The number of speakers with at least 1 COI disclosure increased from 124 of 242 (51.2%) in 2014 to 151 of 216 (69.9%) in 2015 (odds ratio, 2.21; P < .001). The median number of reported COI disclosures increased from 1 (interquartile range [IQR], 0-3) in 2014 to 3 (IQR, 0-8) in 2015 (P < .001). The duration of the COI slide decreased slightly from 6 (IQR, 4-8) to 4.4 (IQR, 2-6.5) seconds.

Figure. Conflicts of Interest (COIs) for Oral Presentations at the 2015 Annual Meeting of the American Society of Clinical Oncology (ASCO)

Reading ability was 4 words per second or below in 62% of presentations and above 4 words per second in 38% of presentations.

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5 (IQR, 2–9) seconds ($P = .02$), and the number of words included increased from 7 (IQR, 7–12) to 13 (IQR, 7–25) ($P < .001$). The median number of words per second increased from 1.5 to 3.2 per second from 2014 to 2015 ($P < .001$). In 2014, no differences were found in the number of COI disclosures between education and oral sessions. In 2015, oral sessions had more conflicts (median, 5.5; IQR, 0.5–11.5) than educational sessions (median, 3; IQR, 0–6) ($P = .004$).

The Figure shows a waterfall plot of words per second in 2015. The baseline is set as 4 words per second, an optimistic estimate of maximum reading ability. In 2014, a total of 37 of 248 presentations (14.9%) had information overload, whereas in 2015 this number increased to 83 of 221 (37.6%) ($P < .001$). As a sensitivity analysis, we compared 2015 and 2013 and reached similar conclusions.

Discussion | We found that the change in policy from disclosure of relevant to all financial COIs increased disclosed COI and information overload at ASCO annual meetings. Of concern, 83 of 221 presentations (37.6%) at last year’s ASCO meeting had COI disclosure slides that were displayed at a speed so fast that they exceeded the range of comprehension for most readers. For COI disclosure to be meaningful, it must be able to be read and processed. We also found that 124 of 242 speakers (51.2%) had at least 1 financial COI, and this number increased to 151 of 216 (69.9%) when all financial ties were disclosed as opposed to only those deemed relevant.

Our findings raise concern about whether current disclosure protocols constitute meaningful disclosure. The solution would be to extend the time of the disclosure slide so that no slide exceeds established limits of reading speed. Further investigation is needed on audience ability to process COI slides at professional meetings if disclosure is the major objective.

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Acquisition, analysis, or interpretation of data: Boothby, Wang, Prasad.

Drafting of the manuscript: Prasad.

Critical revision of the manuscript for important intellectual content: Boothby, Wang, Cetnar.

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Conflict of Interest Disclosures: None reported.

Methods | This study was approved by the institutional review boards of the University of Michigan, University of Southern California, and Emory University. A waiver of documentation of informed consent was obtained, and return of the survey was considered written consent. A total of 3631 women aged 20 to 79 years with newly diagnosed breast cancer (stages I-III) as reported to the Surveillance, Epidemiology, and End Results (SEER) registries of Georgia and Los Angeles County from July 2013 through September 2014 were surveyed a mean of 6 months after diagnosis about their treatment experiences as part of the iCanCare Study (2578 respondents [71% response rate]). Those who had complete information regarding online communication use and their appraisal of decision making (decision satisfaction and deliberation) were included in this analysis (N = 2460).

Respondents were asked how often since their diagnosis they used different forms of communication, including email or texting, social media (such as Twitter, Facebook, and blogs), and/or web-based support groups (5-point Likert scales from “never” to “always”) to discuss their breast cancer diagnosis, treatment, or care. A summary measure was then derived to represent and/or use of the 3 different modalities and categorized into never or rarely, some, or frequent use.

Patient appraisal of decision making was assessed using the established 5-item decision satisfaction scale, categorized into high vs lower satisfaction.1,2 We also evaluated a newly developed 4-item measure of deliberation derived from a measure of public deliberation3 and categorized into more vs less deliberation.

Percentages reported in the Results section are weighted. Bivariate weighted associations between patient demographic

characteristics (age, race, and education) and the frequency of online communication use were evaluated using Rao-Scott χ² tests. Multivariable, weighted logistic regression was then used to estimate the association between the frequency of online communication use and high decision satisfaction and more decision deliberation.

**Results** | The mean (SD) age at survey was 61.9 (0.2) years; 1398 (59.3%) of the cohort were white, followed by black (429 [16.3%]), Latina (429 [16.3%]), Asian (216 [8.3%]), and other/unknown (58 [2.4%]), and 1725 (72.9%) had some college education or more. Overall, 1002 (41.2%) of women reported some or frequent use of online communication, most commonly for email or texting (834 [34.7%]), with less use of social media (305 [12.3%]) and web-based support groups (289 [11.9%]).

Variation in online communication use across age and education existed, with a stronger association between more education and some or frequent online communication use among the younger women (P < .001) (Figure, A). The frequency of any online communication use also varied across race, with the highest proportion of some or frequent use among white and Asian women (610 [45.6%] and 94 [42.7%]), followed by blacks (151 [34.7%]) and Latinas (133 [32.9%]) (P < .001) (Figure, B).

Compared with never-users, women who were frequent online communication users more positively appraised their decision making. They were more likely to report a more deliberative decision (adjusted odds ratio, 1.67; 95% CI, 1.34-2.10) and were also more likely to report high decision satisfaction (adjusted odds ratio, 1.45; 95% CI, 1.06-1.98) (Table).

**Discussion** | Findings from this study suggest that frequent use of online communication may be associated with more positive appraisal of treatment decision making. However, in this sample, online communication use was limited, with most of the use attributed to email and/or texting and less to social media and web-based support groups. The presence of variation across age, race, and education reinforces that barriers exist to incorporating these modalities broadly across patients with cancer. Additional research is needed before these modalities can be leveraged to improve patient care experiences.

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Seasonal Influenza Vaccination in Patients With Chronic Lymphocytic Leukemia Treated With Ibrutinib

Chronic lymphocytic leukemia (CLL) is associated with immune dysfunction. Infections account for up to 60% of deaths in patients with CLL. To lessen infectious complications, immunization against influenza for immunocompromised individuals is recommended. However, patients with CLL have impaired responses to vaccines, which are further reduced by hypogammaglobulinemia and chemotherapy.

Ibrutinib, an irreversible inhibitor of Bruton tyrosine kinase, is approved for the treatment of CLL and other B-cell malignant neoplasms. Bruton tyrosine kinase is essential for B-cell receptor signaling, B-cell maturation, and immunoglobulin synthesis. Inactivating mutations in BTK (OMIM 300300) cause X-linked agammaglobulinemia, an immunodeficiency characterized by severe hypogammaglobulinemia and recurrent infections. In patients receiving ibrutinib, it is unknown whether B cells can mount a humoral immune response to vaccination.

Methods | Influenza vaccination was offered to patients enrolled in a phase 2 trial of single-agent ibrutinib (NCT01500733). Between October 1 and November 21, 2014, a total of 19 patients received 1 dose of inactivated trivalent influenza vaccine containing A/California/7/2009 (A/CA/09; H1N1) pdm09, A/Texas/50/2012 (A/TX/12; H3N2), and B/Massachusetts/2/2012 (B/MA/12) viruses. Patients 65 years or older received Fluzone high-dose vaccine (Sanofi Pasteur). Patients younger than 65 years received Fluzone high-dose or standard-dose Afluria vaccine (bioCSL) depending on availability of the vaccines. Study procedures were approved by the National Heart, Lung, and Blood Institute institutional review board. All patients provided written informed consent.

We measured hemagglutinin inhibition antibody titers before and 3 months after vaccination. Standard criteria were used to define seroconversion (increase in hemagglutinin inhibition titer from <1:10 to ≥1:40 or a ≥4-fold increase in hemagglutinin inhibition titer ≥1:10 at baseline) and seroprotection (hemagglutinin inhibition titer ≥1:40). Infectious symptoms were recorded during the following 6 months. The Centers for Disease Control and Prevention case definition for influenza-like illness was used.

With 19 patients, the study had 87% power to detect a 25% difference in response rate against the null hypothesis (response rate ≤5%) with 1-sided \( P < .05 \) considered significant using a binomial test. Geometric mean titers before and after vaccination and seroprotection rates were compared using the Wilcoxon signed rank test and McNemar test, respectively. Statistical analysis was performed by R, version 3.2.3 (R Foundation for Statistical Computing).

Results | Seroconversion for at least 1 strain was observed in 5 patients (26%; 95% CI, 9.2%-51.2%) and the null hypothesis was rejected (\( P = .002 \)). Seroconversion for the A/CA/09, A/TX/12, and B/MA/12 strains occurred in 3 (16%; 95% CI, 3.4%-39.6%), 5 (26%; 95% CI, 9.2%-51.2%), and 2 (11%; 95% CI, 1.3%-33.1%) patients, respectively.

There were significant increases in geometric mean titers against all 3 viruses (A/CA/09: before vaccination, 19.3 [95% CI, 10.4-35.7]; after vaccination, 27.8 [95% CI, 12.8-60.3]; \( P = .04 \); A/TX/12: before, 17.9 [95% CI, 9.4-34.1]; after, 38.6 [95% CI, 19.3-77.0]; \( P = .002 \); B/MA/12: before, 9 [95% CI, 5.7-14.0]; after, 12.9 [7.5-22.1]; \( P = .02 \)) and in seroprotection rate against the A/TX/12 strain (32% vs 74%; \( P = .004 \)) after vaccination (Table). Influenza vaccination during the 2013-2014 season was not associated with higher prevaccination or postvaccination titers in the 2014-2015 season.

Seven patients (37%) developed influenza-like illness within 6 months of vaccination. One patient had grade 3 infection with influenza A, subtype H3; all other patients had grade 1 or 2 influenza-like illness.

Discussion | To our knowledge, this is the first study reporting immunization response in patients with CLL treated with ibrutinib. In a small cohort of patients, we sought to test the hypothesis that Bruton tyrosine kinase inhibitors abrogate humoral response to antigen. Given our data, additional studies...
are warranted to evaluate whether ibrutinib impairs or improves vaccine response relative to other treatments.

Limitations of the study include a small sample size and incomplete laboratory confirmation of influenza infection. Furthermore, defining an appropriate control group may prove challenging; treatment-naive patients often have immune impairment related to their disease while patients in remission after chemotheraphy may experience the immunosuppressive effects of treatment.7

Conclusions | Our data show that an antibody response to influenza vaccination is permissible in patients receiving single-agent ibrutinib. Up to 74% of patients achieved seroprotective titers against common influenza viruses after vaccination. Consequently, routine immunization against influenza should be considered in accordance with the Centers for Disease Control and Prevention recommendations for immunocompromised patients.2

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Conflict of Interest Disclosures: Dr Wiestner reported receiving research funding from Pharmacyclics, Inc. No other disclosures were reported.

Funding/Support: This work was supported by the Intramural Research Program of the National Heart, Lung, and Blood Institute of the National Institutes of Health. Pharmacyclics provided ibrutinib and research support.

Role of Funder/Sponsor: Pharmacyclics reviewed and approved the study protocol and reviewed and commented on a draft of the manuscript, but had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; or decision to submit the manuscript for publication. Design and conduct of the study was reviewed by the National Heart, Lung, and Blood Institute institutional review board.

Additional Contributions: We thank the patients for participating in this study. Janet Valdez, PA, National Heart, Lung, and Blood Institute, provided clinical support and Susan Soto, RN, MSN, and Amanda Bray, RN, BSN, OCN, National Heart, Lung, and Blood Institute, provided administrative support.

Prostate Cancer Incidence Rates 2 Years After the US Preventive Services Task Force Recommendations Against Screening

We previously reported a substantial decline in early-stage prostate cancer incidence rates from 2011 to 2012 in men 50 years or older residing in areas covered by the population-based Surveillance, Epidemiology, and End Results (SEER) program.1 This pattern coincided with the decline in prostate-specific antigen (PSA) testing in this age group between 2010 and 2013 following the US Preventive Services Task Force recommendation against routine PSA testing in all men in October 2011 in draft form and in May 2012 in final form, which was preceded by a 2008 recommendation against PSA testing in
Whether the decrease in incidence rates persisted through 2013 is unknown.

Methods | The study was based on a deidentified publicly available database and did not require institutional review board review. We obtained incidence data for invasive prostate cancer diagnosed from 2005 through 2013 in men 50 years and older in 18 SEER registries, covering approximately 28% of the US population. Cases were categorized as local/regional or distant stage according to SEER summary stage. We calculated delay-adjusted incidence rates by age (≥50 years, 50-74, ≥75 years), stage (all stages, local/regional, distant), and race/ethnicity (all races, non-Hispanic whites, non-Hispanic blacks) using SEER*Stat software. Rates were age standardized to the 2000 US population and expressed per 100 000 men. Incidence ratios (IRs) and their 99% confidence intervals measuring the relative change in incidence rates between consecutive years (eg, 2005 vs 2006) were calculated using the method of Tiwari et al.

Results | From 2012 to 2013, localized/regional-stage prostate cancer incidence rates per 100 000 men significantly decreased from 356.5 to 335.4 (IR, 0.94; 99% CI, 0.92-0.96) in men aged 50 to 74 years and from 379.2 to 353.6 (IR, 0.93; 99% CI, 0.89-0.97) in men aged 75 years and older (Figure 1). In contrast, incidence rates for distant-stage disease during the corresponding period remained unchanged in both men aged 50 to 74 years (from 15.7 to 16.5; IR, 1.05; 99% CI, 0.96-1.15) and 75 years and older (from 65.8 to 66.4; IR, 1.01; 99% CI, 0.91-1.12) (Figure 2). We found similar results in non-Hispanic whites and non-Hispanic blacks, although the decrease for early-stage disease in blacks was
Discussion  |  Incidence rates for early-stage prostate cancer continued to decline in men 50 years and older in the 18 SEER areas following the US Preventive Services Task Force recommendations against routine PSA testing to all men in 2012, although the decrease from 2012 to 2013 was smaller than that from 2011 to 2012 (6% vs 19%). Simultaneously, as reported before, PSA testing rates between 2010 and 2013 in the United States significantly decreased from 36.8% (99% CI, 34.3%-39.4%) to 29.9% (99% CI, 28.0%-32.0%) in men 50 to 74 years old and from 43.1% (99% CI, 37.1%-49.2%) to 36.3% (99% CI, 31.1%-41.9%) in men 75 years and older.1

Other factors that may have contributed to the decrease in incidence rates for early-stage prostate cancer include changes in the prevalence of risk factors and/or preventive measures. However, as noted in our previous article,4 temporal changes in established risk factors (age, race/ethnicity, and family history) are unlikely to have caused the continued decrease in the incidence rates. Although 5α-reductase inhibitor treatment has been shown to reduce the risk of prostate cancer,6 their use is not recommended for prevention in the general population.

In conclusion, the decrease in early-stage prostate cancer incidence rates from 2011 to 2012 in men 50 years and older persisted through 2013 in SEER registries, albeit at a slower pace. Whether this pattern will lead to a future increase in the diagnosis of distant-stage disease and prostate cancer mortality requires long-term monitoring because of the slow-growing nature of this malignant neoplasm.
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Published Online: August 18, 2016. doi:10.1001/jamaoncol.2016.2667.

Author Contributions: Dr Ma had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
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Acquisition, analysis, or interpretation of data: Jemal, Ma, Siegel, Fedewa.
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Study supervision: Jemal, Brawley, Ward.

Conflict of Interest Disclosures: None reported.

Funding/Support: This project was supported by the Intramural Research Department of the American Cancer Society.

Role of the Funder/Sponsor: The American Cancer Society had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Disclaimer: The opinions expressed are solely the responsibility of the authors and do not necessarily reflect the official views of the American Cancer Society.


COMMENT & RESPONSE

Financial Relationships With Industry Among National Comprehensive Cancer Network Guideline Authors

To the Editor The National Comprehensive Cancer Network (NCCN), as the developer of the most widely used clinical practice guidelines in oncology, takes the integrity of its NCCN Clinical Practice Guidelines development process very seriously. Thus, we read with great interest the article by Mitchell et al,1 in which they assessed financial conflicts of interest (COIs) among 4 of the NCCN Guidelines Panel members in 2014 as documented in the Centers for Medicare & Medicaid Services (CMS) Open Payments database. The NCCN has a robust disclosure policy for panel members restricting participation in panels to individuals who receive up to $20,000 from any individual company and up to $50,000 in the aggregate of all companies for consulting, advising, honoraria, stock ownership, or patents.2 The NCCN excludes travel, lodging, and meals because these funds cover expenses paid to third parties and not the individual. Many of these activities facilitate sharing often unique knowledge to inform development of new therapies. It is known that the Open Payments Database is sometimes inaccurate, so direct queries to panel members who might exceed the NCCN financial COI thresholds according to the Open Payments are important in understanding whether a meaningful COI actually exists. Using the NCCN definition of financial COIs, our analyses found that less than 1% of all panel members, of all panels, exceeded the NCCN financial COI thresholds in 2014 based on the CMS Open Payments Database once adjudicated for accuracy of the database and for excluded payments. The NCCN excludes research funds from its COI analysis because the NCCN believes it is the responsibility of academic physicians to actively participate in research activities, that research should be encouraged, and because most cancer research funding in the United States comes from industry. Generally, research funding is provided to the sponsoring institution to defray costs of the trial and not to individual investigators. As Nipp and Moy3 noted in their accompanying commentary, experts of the type desired by high-quality guideline panels are often the same quality of experts sought by industry for consultation. The talent pool of disease and specificity is very limited. This interaction and sharing of expertise is good for academia, industry, the health care industry, and for patients. We agree with Mitchell et al1 and Nipp and Moy3 that ongoing monitoring and research regarding financial COIs at the interface of academia, medicine, and industry is important.

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Published Online: October 27, 2016. doi:10.1001/jamaoncol.2016.4919

Conflict of Interest Disclosures: Dr Carlson and Ms McClure are employed by National Comprehensive Cancer Network. No other conflicts are reported.


Transparency or Independence in Conflict of Interest Disclosures

To the Editor

Boothby et al observed that slides disclosing conflicts of interest at the meeting of the American Society of Clinical Oncology were displayed at a speed so fast that they exceeded the range of comprehension for most readers. The solution could be to extend the time of the disclosure slide.

This is not discovering warm water because the last sentence of the article, which ended with “if disclosure is the major objective,” is very stimulating and rightly questioned the rational for disclosure.

Indeed, disclosing conflicts seems to be used for dissolving them. Physicians who openly acknowledge their ties tend to make even more extravagant claims about product safety and efficacy, and patients tend to view physicians who declare their ties as particularly “honest.” Moreover, the Sunshine Act exempts authors from reporting several types of payments. Accordingly, disclosure could be a tricky smokescreen.

Transparency is only a tool. Independence is the goal. No one can ignore the fact that pharmaceutical company sponsorship of trials is associated with reduced likelihood of reporting unfavorable results. Misrepresentation of the effectiveness and harms through selective reporting, duplicate publication, and underreporting is evidence-based. Conflict of interests also influence guideline authors in counterproductive ways.

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Published Online: October 27, 2016. doi:10.1001/jamaoncol.2016.4908

Conflict of Interest Disclosures: None reported.


CORRECTION

Error in Results Section: In the article “Postoperative Radiotherapy Patterns of Care and Survival Implications for Medulloblastoma in Young Children” by Kann et al, there was an error in the second paragraph, third sentence of the Results section. The percentage “8.1%” should have read “7.3%”. “PORT deferral increased from 2004 to 2012 (odds ratio [OR], 1.15 per year; 95% CI 1.07-1.24 per year), from a low of 7.3% in 2005 to a high of 27.1% in 2012 (Figure 1).” The article has been corrected online.