Financial associations of public speakers at meetings of other advisory committees, including those for the FDA or the Centers for Medicare & Medicaid Services.

Matthew V. Abola, BA
Vinay Prasad, MD, MPH

Author Affiliations: Case Western Reserve University School of Medicine, Cleveland, Ohio (Abola); Division of Hematology Oncology/Knight Cancer Institute, Department of Public Health and Preventive Medicine, Center for Health Care Ethics, Oregon Health & Science University, Portland (Prasad).

Corresponding Author: Vinay Prasad, MD, MPH, Division of Hematology Oncology/Knight Cancer Institute, Department of Public Health and Preventive Medicine, Center for Health Care Ethics, Oregon Health & Science University, 3181 SW Sam Jackson Park Rd, Portland, OR 97239 (prasad@ohsu.edu).

Published Online: February 1, 2016. doi:10.1001/jamainternmed.2015.7805.

Author Contributions: Mr Abola 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. Study concept and design: Both authors. Acquisition, analysis, or interpretation of data: Both authors. Drafting of the manuscript: Both authors. Critical revision of the manuscript for important intellectual content: Abola. Statistical analysis: Abola. Administrative, technical, or material support: Abola. Study supervision: Prasad.

Conflict of Interest Disclosures: None reported.


Editor's Note

The Financial Associations of Public Speakers at Meetings of Federal Health Advisory Committees

Federal health advisory committees in the United States meet in public. Public speakers who travel to the Washington, DC, or Baltimore areas to attend meetings of the committees that advise the US Food and Drug Administration (FDA) or the Centers for Medicare & Medicaid Services (CMS) often have ties to companies with a financial stake in the outcome of the deliberations. In this issue of JAMA Internal Medicine, Abola and Prasad1 put numbers on a somewhat predictable finding. They analyze the characteristics of speakers at meetings of the FDA’s Oncologic Drugs Advisory Committee and find that a substantial proportion have financial associations with the company seeking marketing approval for a drug or medical device or an organization that receives financial support from the company.1 Most of the financial ties were disclosed, but not all.

It is understandably challenging to attract public speakers without vested interests to undertake the time, travel, and expense involved in attending a federal health advisory committee meeting. At such meetings, these speakers often tell anecdotal stories that, although informative, require evaluation in the evidence-based framework that is an essential part of advisory committee deliberations. The analysis by Abola and Prasad1 also suggests that advisory committee members and federal health officials should recognize that public speakers represent a nonrepresentative sample of speakers who may be biased toward a favorable view of the drug or medical device that is being discussed.

Comments by patients and public speakers are valuable at federal health advisory committee meetings. They offer an additional perspective to those of the patient representatives, in the case of the FDA, and patient advocates, in the case of the Medicare Evidence Development and Coverage Advisory Committee, who serve as members of the committees. A more robust selection system, however, would improve the objectivity and range of input to the FDA and CMS panels that conduct the agencies’ health advisory committee meetings. The FDA has recently initiated new programs to engage patients and to incorporate patient perspectives into its regulatory evaluations and decision-making.2 The FDA, CMS, and other federal health agencies should supplement public comments with systematic information about patient perspectives on medical products and patient-reported outcomes of their use.

Robert Steinbrook, MD

Conflict of Interest Disclosures: Dr Steinbrook was a member of the Medicare Evidence Development and Coverage Advisory Committee from 2010 to 2012.


LESS IS MORE

Osteoporosis Overtreatment in a Regional Health Care System

The US Preventive Services Task Force recommends dual-energy x-ray absorptiometry (DXA) screening for women 65 years or older and for younger women with an elevated risk for fracture.1 However, for women to benefit from this screening, physicians must initiate drug treatment based on the presence of clinically important DXA abnormalities and patient risk. We estimated the frequency of osteoporosis overtreatment in a regional health care system where DXA reports routinely include T scores for anatomic sites (eg, lateral lumbar spine) that the International Society for Clinical Densitometry2 does not recommend for osteoporosis diagnosis.

Methods | We performed a retrospective cohort study using electronic health records (EHRs) and linked radiology records on women aged 40 to 85 years receiving initial DXA screening within the UC Davis health system from January 1, 2006, through December 31, 2011; data analysis was conducted from January 1 to July 31, 2015. The institutional review board at UC Davis approved the study. Data were not deidentified. The
health system includes an academic medical center and a physician group offering primary care at 13 clinics across the Sacramento region. As previously described,3 EHR and radiology databases were searched back through 2002 (the initial year of system-wide EHR implementation) to identify treatment-naive women undergoing initial DXA screening and to classify women by the presence of 1 or more of 6 risk factors: body mass index greater than 20 (calculated as weight in kilograms divided by height in meters squared), glucocorticoid use, possible secondary osteoporosis, previous high-risk fracture (eg, humeral or Colles fractures), rheumatoid arthritis, or alcohol abuse.

We used natural language processing to abstract T scores from EHR radiology reports. For each site, we classified T scores as normal (T > −1.0), osteopenia (−2.5 < T ≤ −1.0), and osteoporosis (T < −2.5). We defined the anterior-posterior spine and femoral neck as main sites because the International Society for Clinical Densitometry7 recommends these for osteoporosis diagnosis. We classified T scores from lateral lumbar, Ward triangle of the hip, and radius sites as non–main sites. Each DXA result was classified as (1) all sites normal, (2) non–main-site osteopenia (with normal main-site bone mineral density), (3) main-site osteopenia (without osteoporosis), (4) non–main-site osteoporosis (without main-site osteoporosis), and (5) main-site osteoporosis. Using EHR prescription data, we identified patients who received new prescriptions for osteoporosis medications during the year of DXA screening or the following year.

We computed the percentages of women in each DXA category, those who received new prescriptions, and new prescriptions in the population attributable to each category. Analysis using χ2 tests was then performed to compare the percentages of women who received new drug therapy by the DXA result (no osteoporosis, non–main-site osteoporosis, and main-site osteoporosis), age, and risk factor status.

**Results** | The sample included 6150 women who underwent initial DXA screening; 1912 of these women (31.1% [95% CI, 29.9%-32.3%]) received new osteoporosis drug treatment. A total of 1254 women (20.4%) had 1 or more osteoporosis risk factors. Overall, 871 women (14.2%) had main-site osteoporosis, 2016 women (32.8%) had non–main-site osteoporosis, and the remaining 3263 women (53.1%) had either isolated osteopenia or normal T scores (Table).
Most women with main-site osteoporosis (73.5% [95% CI, 70.4%-76.4%]) received new drug therapy, as did nearly half of those with non-main-site osteoporosis (47.7% [95% CI, 45.5%-49.9%]) (Figure). Nevertheless, because non-main-site osteoporosis or isolated osteopenia occurred commonly, women with non-main-site osteoporosis accounted for 50.3% of new drug prescriptions (95% CI, 48.0%-52.5%), and those with osteopenia accounted for 15.8% (95% CI, 14.2%-17.5%).

Of the 6150 initial DXAs, 3696 (60.1%) were performed on women aged 40 to 64 years without osteoporosis risk factors who may not have been recommended for screening according to the US Preventive Services Task Force (Table). Of the 1912 women who initiated new drug treatment, 1272 (66.4%) had DXAs either without osteoporosis or non-main-site osteoporosis. Of those 1272 women, 648 (50.9%) were aged 40 to 64 years and had no risk factors. Results were essentially unchanged when analyses were repeated, first, excluding women younger than 50 years or those with previous high-risk fractures, and second, only with DXAs completed from January 1, 2009, through December 31, 2011.

Discussion | Within a regional health care system, two-thirds of new osteoporosis drug prescriptions were potentially inappropriate because the osteoporosis diagnosis was based on DXA abnormalities considered nondiagnostic by international guidelines. Of these potentially inappropriate prescriptions, half were provided to younger women without osteoporosis risk factors who may not have merited screening.

In our population, nearly one-third of the women had non-main-site osteoporosis, which was disproportionately attributable to lateral lumbar spine osteoporosis. These results suggest that either physicians are unaware of International Society for Clinical Densitometry guidelines that lateral lumbar spine bone mineral density should not be used for osteoporosis diagnosis or they assume that osteoporosis observed at any site warrants treatment.

Although two-thirds of new prescriptions in the population were potentially inappropriate, some higher-risk patients with non-main-site osteoporosis or osteopenia may elect to begin drug treatment. We also acknowledge the limitation of potential inaccuracy of EHR-derived variables. However, these issues are unlikely to account for the observed extent of overtreatment.

Our findings are from one regional health care system and may not generalize to others that do not report T-scores at nondiagnostic sites. Our system recently ceased reporting lateral lumbar spine and the Ward triangle T-scores determined on DXA screenings. To avert osteoporosis overtreatment, health care systems should either ensure that radiologists report T scores only for sites consistent with International Society for Clinical Densitometry diagnostic guidelines or provide high-quality decision support so that physicians do not make osteoporosis diagnoses based on nondiagnostic sites.

Joshua J. Fenton, MD, MPH
John A. Robbins, MD, MSH
Anna Lee D. Amarnath, MD, MPH
Peter Franks, MD

Invited Commentary

Variability in DXA Reporting and Other Challenges in Osteoporosis Evaluation

A 65-year-old woman undergoes routine screening dual-energy x-ray absorptiometry (DXA), which reveals T scores of −2.3 at the femoral neck, −2.7 at the Ward triangle, −2.2 at the total hip, and −1.9 at the posterioranterior (PA) lumbar spine. Evaluation reveals no secondary cause of osteoporosis. She asks whether you recommend medication for osteoporosis. Osteoporotic fractures—hip fractures in particular—are associated with tremendous medical and economic effects. Bone mineral density (BMD) is the best predictor of fracture in the absence of prior fracture, and thus DXA is a crucial tool for identifying patients at high risk. Unfortunately, the quality of DXA reporting is variable, and misleading information may result