

## Ethics of Commercial Screening Tests

Erik A. Wallace, MD; John H. Schumann, MD; and Steven E. Weinberger, MD

Recent publications have emphasized the importance of physicians taking a leading role in delivering patient-centered, high-value, cost-conscious care (1–3). Scientifically valid preventive services, 19 of which were recently endorsed by the National Quality Forum (4), improve the health of the population and reduce costs by means of avoidance of expensive care for advanced disease. Low-cost screening for hypertension, dyslipidemia, diabetes, and tobacco use and treatment with lifestyle modification and medications can prevent more than 50% of heart attacks and strokes (5). However, the increasing availability of direct-to-consumer screening tests is undermining physician efforts to provide high-quality, cost-conscious screening services to patients through shared decision making.

Commercial companies may offer various screening tests, some with proven benefit, such as measurement of blood pressure and blood sugar and lipid levels. However, we are particularly concerned about the misapplication of technology, such as the use of ultrasonography (for example, ultrasonography of the carotid arteries to assess for plaques and stenosis, ultrasonography of the heel to assess for osteoporosis, and echocardiography) in the direct-to-consumer screening market as a driver of expensive and unnecessary care. Although popular with consumers and physicians alike, technology has contributed to a substantial increase in health care costs (6), and patients are increasingly demanding testing from their physicians (7).

Purveyors of these services have sprouted up all over the country, selling “packages” of screening tests outside of the traditional physician–patient relationship at “discounted” prices. Tests are offered at various locations, including churches, pharmacies, fitness centers, and shopping malls, often with a local hospital, academic medical center, or physician group as an advertising sponsor. Some companies use endorsements from celebrities, board-certified physicians, and such agencies as the Better Business Bureau to endorse the benefits of purchasing screening tests. Ultrasonography and other tests are marketed as “safe” and “harmless” to consumers because they do not use radiation or require needlesticks.

Anyone can purchase these tests—regardless of age or risk factors for disease or whether testing is truly indicated—if they are willing to pay the advertised fee. When screenings are provided in a church and sponsored by a trusted medical organization, consumers may have a false sense of trust in the quality and appropriateness of services provided. Consumers are generally unaware of the potential harms of screening (8).

In the conventional medical model, physicians or extenders *should* discuss age-appropriate screening tests in asymptomatic persons *before* ordering such testing. We acknowledge that, in many instances, suboptimal or no dis-

ussion takes place given the time constraints of routine office practice (9). Companies, through waivers and disclaimers, tell consumers to share any “abnormal” test result with their physicians; however, the specific risks and costs of potential downstream testing and treatment are generally not discussed when the screening tests are purchased and performed.

Because of a lack of counseling by these companies about the potential risks of an “abnormal” test result, the consumer is initially unaware that this may open a Pandora’s box of referrals and additional testing to monitor or treat these abnormal findings. Our medical system and society bear the cost of poor coordination of care and additional testing and treatment to follow up on unnecessary “abnormal” screening test results (10). That most of these tests are not medically indicated in the first place is left undisclosed to the consumer, nor is there a discussion of potential adverse consequences or additional costs.

At a minimum, ethical considerations require that direct-to-consumer screening companies state openly for whom such screening tests are indicated on the basis of published, evidence-based guidelines; companies offering such screening tests fully inform customers of the potential risks of positive or negative screening test results before any testing is performed; and medical organizations, hospitals, and physicians refrain from sponsoring health screenings with commercial companies that offer unproven or harmful testing because it represents a clear conflict of interest. Some physicians have decried the way that medical centers sponsor such tests as a means of feeding business to high-overhead services (11).

Commercial screening companies promote the success of their products with numerous testimonials. Anecdotally, some patients actually have clinically significant disease detected before the onset of symptoms, leading to effective treatment that reduces morbidity and mortality. Others may have received an indicated screening test that insurance in conventional medical practice would have covered (such as abdominal aortic ultrasonography in men aged 65 to 75 years who previously smoked) (12).

Advocates of widespread screening may argue that if patients know that they have disease, they will be more likely to engage in behavior modification. However, evidence does not support this hypothesis. As an example, although patients who smoke and are interested in quitting have a high prevalence of carotid stenosis, those with abnormal results on carotid ultrasonography are no more likely to quit smoking than those with normal results or those who did not have an ultrasonography (13). Most commercial screening companies offer carotid ultrasonography, but the U.S. Preventive Services Task Force recommends against screening the general adult population for

carotid artery stenosis because there is a moderate or high certainty that there is no net benefit or that the harms outweigh the benefits (14).

If screening asymptomatic persons in the general population with nonindicated tests neither is medically beneficial nor enhances behavior change, how can it be ethical to allow marketing of such tests to the public? We believe that promoting and selling nonbeneficial testing violates the ethical principles of beneficence and nonmaleficence (15). Although commercial screening services seem to respect patient autonomy, the failure to fully disclose the appropriate indications and consequences of testing is deceptive, because patients purchase these services with a false hope of benefit. Appropriate and truly informed consent cannot be obtained when the companies providing the test do not fully disclose the potential risks and lack of benefit before collecting payment and performing the tests.

We respect patients' autonomy to make their own medical decisions. However, choices should be informed by evidence, not such advertising claims as, "the ultrasound screenings that we offer can help save your life." Patients can be coerced through unsubstantiated, misleading statements or omission of factual information into obtaining tests where the actual risk may outweigh the proven benefit. In direct-to-consumer advertising of pharmaceuticals, companies are required to disclose the potential risks of taking a medication. We believe that commercial screening companies should also be obligated to disclose from published guidelines the recommended indications and benefits of testing, as well as the potential risks and harms.

Judicious and appropriate use of preventive services can certainly improve the health of our population and lower overall health care costs. However, misuse of preventive services, under the guise of saving lives and saving costs, may actually lead to increased cost and harm due to unnecessary follow-up testing and treatment with associated avoidable complications. We suggest that medical entities and physicians withdraw from the unethical business of promoting unproven and potentially harmful screening tests.

From the University of Oklahoma School of Community Medicine, Tulsa, Oklahoma, and American College of Physicians, Philadelphia, Pennsylvania.

**Potential Conflicts of Interest:** Disclosures can be viewed at [www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M12-0927](http://www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M12-0927).

**Requests for Single Reprints:** Erik A. Wallace, MD, Department of Internal Medicine, University of Oklahoma School of Community Medicine, 4502 East 41st Street, Tulsa, OK 74135; e-mail, [erik-wallace@ouhsc.edu](mailto:erik-wallace@ouhsc.edu).

Current author addresses and author contributions are available at [www.annals.org](http://www.annals.org).

This article was published at [www.annals.org](http://www.annals.org) on 28 August 2012.

## References

1. Cooke M. Cost consciousness in patient care—what is medical education's responsibility? *N Engl J Med*. 2010;362:1253-5. [PMID: 20357275]
2. Qaseem A, Alguire P, Dallas P, Feinberg LE, Fitzgerald FT, Horwitch C, et al. Appropriate use of screening and diagnostic tests to foster high-value, cost-conscious care. *Ann Intern Med*. 2012;156:147-9. [PMID: 22250146]
3. Cassel CK, Guest JA. Choosing wisely: helping physicians and patients make smart decisions about their care. *JAMA*. 2012;307:1801-2. [PMID: 22492759]
4. National Quality Forum. NQF endorses prevention care and screening measures [press release]. 3 May 2012. Accessed at [www.qualityforum.org/News\\_And\\_Resources/Press\\_Releases/2012/NQF\\_Endorses\\_Prevention\\_Care\\_and\\_Screening\\_Measures.aspx](http://www.qualityforum.org/News_And_Resources/Press_Releases/2012/NQF_Endorses_Prevention_Care_and_Screening_Measures.aspx) on 22 May 2012.
5. Frieden TR, Berwick DM. The "Million Hearts" initiative—preventing heart attacks and strokes. *N Engl J Med*. 2011;365:e27. [PMID: 21913835]
6. Blumenthal D. Controlling health care expenditures. *N Engl J Med*. 2001;344:766-9. [PMID: 11236784]
7. Brett AS, McCullough LB. Addressing requests by patients for nonbeneficial interventions. *JAMA*. 2012;307:149-50. [PMID: 22235082]
8. Woolf SH, Harris R. The harms of screening: new attention to an old concern. *JAMA*. 2012;307:565-6. [PMID: 22318274]
9. Yarnall KS, Pollak KI, Østbye T, Krause KM, Michener JL. Primary care: is there enough time for prevention? *Am J Public Health*. 2003;93:635-41. [PMID: 12660210]
10. Berwick DM, Hackbarth AD. Eliminating waste in US health care. *JAMA*. 2012;307:1513-6. [PMID: 22419800]
11. Brawley O, Goldberg P. *How We Do Harm: A Doctor Breaks Ranks about Being Sick in America*. New York: St Martin's Pr; 2011.
12. U.S. Preventive Services Task Force. Screening for abdominal aortic aneurysm: recommendation statement. *Ann Intern Med*. 2005;142:198-202. [PMID: 15684208]
13. Rodondi N, Collet TH, Nanchen D, Locatelli I, Depairon M, Aujesky D, et al. Impact of carotid plaque screening on smoking cessation and other cardiovascular risk factors: a randomized controlled trial. *Arch Intern Med*. 2012;172:344-52. [PMID: 22269590]
14. U.S. Preventive Services Task Force. Screening for carotid artery stenosis: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2007;147:854-9. [PMID: 18087056]
15. Snyder L; American College of Physicians Ethics, Professionalism, and Human Rights Committee. *American College of Physicians Ethics Manual*: sixth edition. *Ann Intern Med*. 2012;156:73-104. [PMID: 22213573]

**Current Author Addresses:** Drs. Wallace and Schumann: Department of Internal Medicine, University of Oklahoma School of Community Medicine, 4502 East 41st Street, Tulsa, OK 74135.  
Dr. Weinberger: American College of Physicians, 190 N. Independence Mall West, Philadelphia, PA 19106.

**Author Contributions:** Conception and design: E.A. Wallace, J.H. Schumann, S.E. Weinberger.  
Drafting of the article: E.A. Wallace, J.H. Schumann, S.E. Weinberger.  
Critical revision of the article for important intellectual content: E.A. Wallace, J.H. Schumann, S.E. Weinberger.  
Final approval of the article: E.A. Wallace, J.H. Schumann, S.E. Weinberger.