

# The Harms of Screening

## New Attention to an Old Concern

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**A**MERICANS ARE ENTHUSIASTIC ABOUT SCREENING, ESPECIALLY cancer screening.<sup>1</sup> What could be wrong with screening, especially if it can detect a life-threatening condition at an earlier stage? Trials show that early detection of breast, colorectal, and other cancers can reduce cause-specific mortality rates, and the same could apply to other conditions. With presumably little to lose and much to gain from early detection, why recommend against screening unless the concern is costs? Are lives being lost to save money?

But costs are rarely the reason that guidelines set limits on screening. Most screening controversies turn on how to balance potential harms relative to potential benefits. Harms from screening programs are real; the burden of these harms can be disputed, but their existence cannot. Screening can produce iatrogenic complications (eg, perforation from colonoscopy), anxiety over abnormal results, and a cascade of follow-up tests and treatments. Screening can also precipitate overdiagnosis, the workup and treatment of conditions that qualify as disease but pose little threat to patients' health.

Concerns about the harms of screening might seem exaggerated without closer scrutiny. For instance, if a test with 90% sensitivity and 96% specificity (better than most screening tests) is used to screen for a condition with a prevalence of 0.6% (typical of some cancers), 88% of abnormal results will be erroneous; for every 1000 patients screened, only 6 will have the condition and 40 will have false-positive results. That ratio may be acceptable if the benefits obtained by the 6 patients with true disease outweigh the harms incurred by the 1000 patients who undergo screening, but what if there is little evidence that early detection improves their prognosis? If only 1 or 2 of the 6 patients obtain benefit, is it ethical to subject the entire population to screening? The concern about overdiagnosis is justified: by some estimates, overdiagnosis accounts for 15% to 25% of screen-detected lung cancers<sup>2</sup> and potentially more breast and prostate cancers.

Whether the harms are important enough to limit screening has been a vociferous debate for decades. In the 1980s, the most cautious groups—notably the US Preventive Ser-

vices Task Force (USPSTF)—broke sharply with proponents of screening. Skeptics argued that the potential harms made it unethical to recommend screening without compelling scientific evidence of meaningful benefits (eg, lower morbidity/mortality). The proponents (eg, American Cancer Society, American College of Radiology) dismissed concerns about harms and warned that waiting for definitive evidence would cost lives.

In the 1990s, the opposing parties found middle ground as both the science and respect for harms became stronger. In 1992, citing mounting evidence of benefits, the USPSTF abandoned its earlier skepticism and endorsed fecal and sigmoidoscopy screening for colorectal cancer. In 2000 and 2001, respectively, the American Urological Association and American Cancer Society recommended that men obtain information about harms before undergoing prostate-specific antigen (PSA) screening. In 2002, the USPSTF added colonoscopy as a screening option and abandoned its opposition to mammography screening for women 40 years and older. However, a largely unnoticed caveat in the 2002 mammography guideline revealed continuing concern about harms: “The precise age at which the benefits from screening mammography justify the potential harms is a subjective judgment and should take into account patient preferences. Clinicians should inform women about the potential benefits . . . , potential harms . . . , and limitations . . . that apply to women their age.”

In 2008, the apparent consensus in guidelines began to unravel. Two colorectal cancer screening tests that the USPSTF found lacking in evidence—fecal DNA testing and computerized tomographic colonography—were endorsed by the American Cancer Society and medical specialty societies. In 2009, the USPSTF issued a controversial recommendation against “routine” mammography among women aged 40 to 49 years. Amplifying its earlier caveat, the USPSTF urged women of this age group to first make an informed decision with their physician that considered individual clinical context and “the patient’s values regarding specific benefits and harms.” In 2011, concern about

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known harms and uncertain benefits prompted the USPSTF to circulate a draft recommendation against PSA screening.

The USPSTF is not alone in its concern about harms. In 2009, the American College of Obstetricians and Gynecologists recommended postponing Papanicolaou testing until age 21 years and extending the rescreening interval from 1 to 2 years, citing concern about harms.<sup>3</sup> In October 2011, the American Cancer Society and 2 pathology societies recommended that women reduce the lifetime number of Papanicolaou tests to ensure that they “receive the benefits of testing while minimizing the risks.”<sup>4</sup> In November 2011, the American Cancer Society’s chief medical officer echoed the USPSTF concern about the harms of PSA screening.<sup>5</sup> In December 2011, the American Cancer Society published new methods for developing screening guidelines that included a clearer description of harms.<sup>6</sup> Discussion of overdiagnosis has spread from professional journals to lay books<sup>7</sup> and newspapers.<sup>8</sup>

Although this tempo is increasing, some organizations and many patients remain unconcerned about the harms of screening.<sup>1</sup> This question remains: how much weight do the harms of screening rightly deserve? Guideline panels necessarily engage in the subjective exercise of deciding for populations whether the weight of harms is substantial or trivial, but individuals may have different judgments. Ideally, when views differ considerably about the trade-off between harms and benefits, guideline panels should eschew blanket recommendations and promote informed or shared decision making. This approach presents patients with the facts and allows them to reach their own decisions based on personal values and circumstances.

This approach, however, brings its own problems. Expert groups may dispute the “facts”; the science can be difficult for physicians to communicate and for patients to understand; some patients demure and want the physician to decide; physicians may lack the time, reimbursement, or motivation to engage in long discussions; and social attitudes and medicolegal pressures may influence the decision.

Weighing benefits and harms may even be irrelevant to the cognitive process by which patients make decisions; social norms, fears, intuition, or advice from trusted individuals may override concern about harms. In addition, as the USPSTF learned from the 2009 mammography controversy, recommending that physicians abandon a population testing rubric to encourage individual decision making is easily misread as a recommendation “against” screening.

It is not possible to predict whether greater awareness of harms will dampen patients’ enthusiasm for dubious screening tests. More realistically, resource limitations will intervene: profligate screening practices will become increasingly unaffordable in a society struggling with spiraling health care costs. However, society’s first concern should be to confirm that screening is a net good for public health. This requires harms to be considered independently of costs. Until the reality of harms becomes more palpable to clinicians and the public, concerns about the safety of screened populations will continue to be mistaken for frugality.

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