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COMMENTARY

Uninformed Compliance or Informed Choice? A Needed Shift in Our Approach to Cancer Screening

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It has been more than 30 years since the first consensus development meeting was held to deal with guidelines of mammography screening. Although the National Cancer Institute has wisely focused on the science of screening and of screening benefits vs harm, many professional organizations, advocacy groups, and the media have maintained a focus on establishing who should be screened and promoting recommendations for which age groups should be screened. Guidelines have been developed not only for mammography but also for screening at virtually all major cancer sites, especially for prostate cancer, and most recently, with the preliminary results of the National Lung Screening Trial, for lung cancer. It seems clear that we have done an inadequate job of educating screening candidates about the harms and benefits of cancer screening, including the extent to which screening can reduce cancer mortality. We must also question whether our practice of summoning women to have mammograms, while providing men informed choice for prostate cancer screening, is consistent with a scientific analysis of the relative harms and benefits. We have spent a staggering amount of time and energy over the past several decades developing, discussing, and debating guidelines. Professional and advocacy groups have spent much time aggressively advocating the adoption of guidelines supported by their respective groups. It seems that it would be much more productive to devote such energy to educating screening candidates about the harms and benefits of screening and to engaging in shared decision making.

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After the blitz of outrage and commentaries following the US Preventive Services Task Force (USPSTF) recommendations against routine mammography screening for women aged 40–49 years in November 2009 (1), it was perhaps naive to believe that this issue would simply fade away; it was destined to smolder, at least until the next set of screening guidelines prompted yet another hailstorm of criticism. Since the USPSTF breast cancer screening recommendations were announced, science has provided us with findings related to lung cancer, prostate cancer, and even breast cancer screening that should prompt us to consider a new approach to our long history of in-fighting over screening guidelines. Such in-fighting neither makes best use of our professional resources nor serves to enhance the trust and confidence that the public holds for medicine and science.

Recent Breast, Prostate, and Lung Cancer Screening Trial Results

Since the USPSTF breast cancer screening recommendations and ensuing controversy, the results of screening studies have been published that examine the harms and benefits of screening across cancer sites. These have included major studies of breast, prostate, and lung cancer screening.

The most recent USPSTF breast cancer screening recommendations were issued in 2009, based in part on the results from a meta-analysis published since the previous screening recommendations (2). After these most recent USPSTF recommendations, results from the Norwegian breast cancer screening program were published (3), which were based on mammography screening data from 40 075 women with breast cancer. Although this study was not a randomized controlled trial of mammography, it did compare breast cancer–specific mortality in women aged 50–69 years in screened groups vs those in an unscreened group, and it found a small and statistically nonsignificant reduction in breast cancer mortality in the screened groups. The Norwegian findings have done little to provide definitive answers and hush the crowd.

There is similar ambiguity in the evidence regarding prostate cancer screening. The Göteborg randomized population-based prostate cancer screening trial (4), from one of the centers included in the European Randomized Study of Screening for Prostate Cancer (ERSPC), examined the impact of prostate-specific antigen (PSA) testing on mortality reduction. In this study, 20 000 men who were born between 1930 and 1944 were randomly assigned to a group that was invited for PSA testing every 2 years or to a control group that was not tested. The primary endpoint was prostate cancer–specific mortality. The results indicated that prostate cancer–specific mortality was reduced by almost half during 14 years of follow-up. However, a systematic review and meta-analysis of randomized controlled trials focused on prostate cancer screening (5) found that prostate cancer screening did not improve prostate

cancer–specific mortality or overall mortality. It analyzed six randomized trials that met inclusion criteria, including the Göteborg trial, with a total of 387 286 participants and reported important methodological concerns across all trials. To demonstrate the complexity of the findings reported to date, the authors noted that two major studies had substantially different results. The ERSPC study published after the third interim analysis (6) showed a statistically significant benefit for screening, whereas the Prostate, Lung, Colorectal, and Ovarian (PLCO) study (7) was stopped because of concerns of potential net harm. Finally, a recent report (8) of a population-based randomized controlled trial conducted in Norrkoping (Sweden) noted no statistically significant reduction in mortality from prostate cancer. Although the authors concluded that screening could lead to a reduction in prostate cancer–specific mortality of up to one-third, they concurred with others that overdiagnosis and overtreatment would accompany such a possible reduction and pose a major barrier to effective screening. In October of this year (2011), the USPSTF came to similar conclusions and issued recommendations against PSA testing in healthy men while noting conflicting results in the two largest and highest quality studies noted above (6,7).

The National Lung Screening Trial (NLST) (9) examined the impact of screening on deaths from lung cancer among a large (n = 53 456) randomized population of heavy smokers aged 55–74 years. Early results found a 20% relative decrease in lung cancer deaths (or an absolute difference of about 0.3%) among subjects who were randomly assigned to receive computed tomography (CT) scans compared with those who received a standard chest x-ray. These results translated to roughly one life extended for every 300 study participants screened with CT. However, greater than 96% of the positive screening results in the low-dose CT group and greater than 94% in the radiography groups were false positives.

As it was noted almost a decade ago (10), there will come a time when all the patients will have been followed, all the analyses done, all the groups assembled, and all the editorials written, and we still will not be secure in our knowledge of the individual harms and benefits of cancer screening. It appears that this time has come. With the recent appearance of even more meta-analyses of the benefits of cancer screening (11,12), perhaps we should now reexamine our practice of devoting substantial time and resources to debate, develop, and promote heterogeneous and inconsistent guidelines as a key component of cancer control.

The Data: Benefits and Harms

What have the studies to date shown us about the harms and benefits of screening for breast, prostate, and lung cancer that might lead us to consider a new approach? We have some sense of the magnitude of false-positive results in repeated multimodal cancer screenings (13). Data analyzed from the PLCO Cancer Screening Trial (7) across 14 screening tests involving prostate, lung, colorectal, and ovarian cancer over a 3-year screening period found the risk of a false-positive finding to be about 50% by the 14th test. That is, for an individual receiving multimodal cancer screening for several cancers, the risk of a false-positive finding is about 50% or greater by the 14th screening test. This, of course, may result in further diagnostic interventions and/or treatment.

Breast cancer screening risks and benefits vary by age. More than 1900 women aged 40–49 years would need to be invited for mammography screening to prevent one death during 11 years of follow-up, and about 2000 false-positive mammograms and two false-negative mammograms would be generated over these 11 years, along with the resulting unnecessary biopsies, overdiagnosis, and overtreatment (1,14,15). Even among women aged 50–70 years, for whom mammography has been least controversial, 838 women must undergo screening for 6 years to avert one breast cancer death (16). About five in every 1000 women aged 50–59 years will die of breast cancer over the next 10 years. Annual screening over those 10 years would reduce that number to about four deaths, meaning that 999 women screened for 10 years will have gained nothing, and may have been subject to as many as 50% false-positive tests, unnecessary biopsies, overdiagnosis, and overtreatment for breast cancer (1,14,17).

Prostate cancer screening also comes with a mix of harms and benefits. The Göteborg trial (4), which reported a follow-up of 14 years, indicated that in the presence of screening, prostate cancer mortality was reduced by almost half, with 293 men needed to be invited for screening and 12 diagnosed to prevent one prostate cancer death. This estimate was even more optimistic than that from its parent, the recent ERSPC randomized trial (6), which found that 1410 men would need to be screened and 48 additional prostate cancers treated to prevent one death from prostate cancer. Both of these prostate cancer studies produced numbers that are not strikingly different in terms of harms vs benefits than those from the mammography studies summarized above, including those for women in the 50–59 age group, for whom virtually all guidelines merge in recommending routine mammographic screening. However, different conclusions were reached for prostate cancer screening: A recent Cochrane Review (18) concluded that there was insufficient evidence to either support or refute routine prostate cancer screening, and the recent meta-analysis of six randomized trials (5), while noting substantial methodological limitations, found no statistically significant decrease in deaths from prostate cancer as a result of screening.

When it comes to lung cancer screening, the potential harms are enormous in comparison to the potential benefits. Again, more than 94% of all positive screening results were false positives. False-positive findings may possibly lead to radiation exposure from follow-up scans, lung biopsies, and perhaps even risky surgery. Already, discussions about the implication of the NLST on lung cancer screening and marketing of CT scan centers have begun (19). As we learn more about the results of the trial, including the harms and effects on quality of life, and as data from other ongoing studies are published (20,21), there is little doubt that some professional and advocacy groups will dive into the seemingly endless routine of collecting experts, developing guidelines, and promoting their conclusions.

Serving the Public

How well have we served the public by promoting our litany of guidelines, engaging in public debates, and disseminating our beliefs regarding who should be screened and when? What have we taught screening candidates about cancer screening? What do

they understand about the value of screening for cancer after decades of hearing intermittent heated disagreement? We know that the public embraces the idea of screening. They overwhelmingly believe that screening is almost always a good idea and that finding cancer early saves lives (22,23). In fact, one study found that 73% of respondents would prefer to receive a total body CT scan than receive $1000 in cash (22). They are sold on the benefits of screening and are biased toward it even in circumstances without evidence of benefit. We know that many women overestimate their risk of breast cancer, and in scientific articles about mammography (24) as well as patient-oriented brochures (25), there is a tendency to emphasize benefits much more than harms. Women are aware and tolerant of the possibility of false-positive tests but have little knowledge about ductal carcinoma in situ and the possibility of overdiagnosis and overtreatment (26,27).

The public often greatly overestimates the mortality reduction associated with screening for cancer. Even among individuals who have discussed the issue of cancer screening with health-care providers, it is very common that the preferences of the patients are not solicited and that the benefits of screening are presented by the provider much more often than the harms (23). There has been mixed support of cancer screening in the media relative to prostate cancer and mammography for women under age 50, which adds more confusion to the decision-making process. There is evidence that ambiguity about breast cancer screening, at least in terms of mammography recommendations, may affect screening uptake and increase worry among screening candidates (28). Moreover, to further complicate this issue of ambiguity and guidelines, a recent article (29) noted that the mammography guidelines for women aged 40–49 were of sufficiently poor quality that consumers of such guidelines should be aware of the variability in quality.

With respect to PSA screening for prostate cancer, there has been more negative coverage in the United States (at least recently) than in the United Kingdom (30). Data suggest that the public also overestimates survival from lung cancer and thinks of lung cancer screening as an effective means to improve treatment outcome (31): A finding that was reported even before initial results from the NLST trial were reported and a position that is clearly inconsistent with the evidence. Finally, most people are poorly informed about screening, even when they report feeling well informed (23).

Based on these observations, we have done a dismal job of accurately informing the public about screening. Despite all of our attention to early detection and our ongoing debates about cancer screening guidelines, the public still lacks basic knowledge about the benefits and harms of screening. They are often presented a lopsided view of the pros and cons of screening, and, at least in the case of mammography, they have been strongly encouraged to be screened rather than informed. Our less than transparent presentation of data about known harms and benefits has resulted in a bias toward screening in the case of mammography, and an inflated view of how much of the reduction in cancer mortality can be rightfully attributed to cancer screening overall. Guidelines have typically recommended that men make informed decisions about prostate cancer screening, whereas we have summoned women to breast cancer screening. We have unintentionally adopted a very paternalistic stance.

So, the mammography war moves into its fourth decade, the prostate cancer screening controversy plunges ahead, and the issue of lung cancer screening heats up with the NLST publications and data from ongoing trials likely to appear in the near future. It does not end there. A blood test that may be able to detect a single cancer cell among millions, a "liquid biopsy," is in its early stages of development (32). New techniques like this one are exciting and potentially huge steps in our approach to cancer, but they are still years away from any real life application in screening and proof of benefit, and they will also result, to some degree at least, in false positives, false negatives, overtreatment, undertreatment, and costs both in terms of dollars and risks to quality of life. New techniques will also be likely to lead to discussions of the pros and cons of such "screening" tests, and perhaps more guideline battles, not unlike those we have experienced for decades with mammography. Is this the best way to serve the public?

One might argue that such discussions and debates are to be expected in evidence-based medicine. Discoveries are made, challenged, confirmed, or disproved; the science is translated to patient care; and science moves on. However, the discussions and debates in this case are about the "application" of scientific findings, filtered through strong preexisting belief systems of politicians, advocates, health-care providers, and the public. Biases are created and nurtured by our inability or unwillingness to present the data in a transparent fashion and to encourage shared decision making by informed health-care providers and screening candidates. We can do better. It is time to consider a more reasonable simple approach.

A Plan for Action

How do we shift our approach to cancer screening? It seems to me that we should 1) decide to refocus on educating, rather than persuading, the public, 2) engage patients in shared decision making, 3) work together to devise educational tools, 4) measure success in terms of the number of patients informed rather than by the number of patients screened, and 5) support additional research to identify prognostic biomarkers that will permit us to judge which screen-detected lesions will be most dangerous.

First, advocacy organizations must focus on educating health-care providers, cancer patients, and the public, rather than on persuading them to take a specific course of action or engaging in establishing normative prescriptive guidelines. It is virtually impossible for organizations to claim that they engage in "evidence-based" medicine when they also must be sensitive to advocacy groups and public sentiment because they depend on the opinions of these groups for their very existence. In a recent editorial about prostate cancer screening (33), Otis Brawley, Chief Medical Officer of the American Cancer Society, noted that we need to be true to the science and that we should appreciate the truth and explain it as clearly as possible. This principle requires informing screening candidates that both prostate cancer and breast cancer screening have potentially substantial harms. However, the American Cancer Society recommends and advocates strongly for mammography while promoting new prostate cancer screening guidelines that recommend an informed decision-making process. Very little transparent "educational" information about the harms

of mammography is provided on the American Cancer Society website (34).

Second, we need more energy to be spent on promoting shared decision making by health-care providers. The "normative shared decision-making" model (35), in which a decision aid is used and discussed, fits the proposed need for a new approach to cancer screening, as opposed to the current method, that is, directing screening candidates to get screened or not without adequate discussion of the science behind the screening test, including benefits and harms. In the proposed new approach, patients would be provided with clear cancer incidence, mortality, and screening effectiveness data in terms of absolute rates or frequencies, in a way that maximizes understanding of these numbers. Thus, physicians and advocates with a bias to screen or not to screen can certainly voice their opinions but only with clear comprehensible information in front of patients that notes the harms and benefits of cancer screening.

As we move forward in a scientific manner, isn't it time to pilot a new paradigm for cancer screening in a way consistent with the shift in health care toward shared decision making (35)? The alternative is to flail away with the same marketing approaches used for decades as we wait for a consensus on what is known and what is not, what constitutes evidence and what does not.

Third, key scientific and advocacy organizations involved in cancer screening and decision making, along with organizations representing primary care providers, need to work together but not with the goal of establishing guidelines. Rather, this partnership should work on devising the most transparent and easily understood format(s) of presenting the harms and benefits of cancer screening across cancer sites for use by health-care providers and screening candidates. There are a host of decision aids currently available, including those noted by the National Cancer Institute as Research Tested Intervention Programs (RTIPs) that could form a solid base for discussion, dissemination, or, as needed, further evaluation (36). Much of how to do this is known, although further work with a comparative effectiveness focus would be helpful. To a large extent, we simply need to apply what we already know.

Fourth, as we examine screening behaviors, our outcome measures need to focus not on how many candidates obey our "summons" to screen (or not) but rather how many have been successfully engaged in the process of informed decision making. This requires more work to develop and test validated measures of informed choice (37) that will be needed to evaluate interventions to assess informed decision making among screening candidates. The development and refinement of such instruments could help to encourage health-care providers to be accountable in delivering a shared decision-making model while also helping individuals to make optimal personal decisions (37). Such an instrument could be applied as a metric to determine the degree of shared decision making involved in cancer screening decisions not only in the research domain but also in the clinical world. That is, rather than using "adherence" to screening measures to direct quality of care indices and pay for performance initiatives, perhaps we might track how many patients are provided the information related to harms and benefits of screening as the "gold standard" of patient care?

Fifth, synchronously with the above, and critically important, we need to energize work to identify markers that discriminate minimal-risk disease likely to have little impact on mortality vs high-risk disease (16). The degree to which we are successful doing so will of course have an important impact on the harm to benefit ratio of all cancer screening strategies.

Logistical Considerations

Arguments can be raised that there are limitations to the approach of educating patients. Will shared decision-making result in any better outcomes? Will decisions made from the perspectives of each individual patient necessarily translate into better outcomes for the population as a whole? Will giving patients more allowance to opt out of screening exacerbate health disparities? These are considerations that deserve some thought, and in each case, I think that patient education can be tailored in such a way that these issues will not be problems.

Although some patients' abilities to digest highly technical information may be limited, the presentation of pertinent information regarding cancer screening need not be complicated, and there is no reason to think that shared decision making will not work for the vast majority of patients.

Some might argue that what is deemed best by an individual patient might not be what is best for the population as a whole. From a public health perspective, mammography and prostate cancer screening could be considered effective by simply multiplying the lives saved over an entire population. However, this argument to date has not fully considered the public health implications of the harms of screening. As noted previously, among women aged 40–49 years, more than 1900 women would need to be invited for mammography screening to prevent one death during 11 years of follow-up, typically resulting in about 2000 false-positive and two false-negative mammograms, along with unnecessary biopsies, overdiagnosis, and overtreatment (1,14,15). Doing the math on a national public health basis provides staggering numbers in terms of human costs.

A public health perspective on decision making for screening also fails to take into account individual factors that may play a role in such decision making. Factors such as personal and family medical history, cancer-related anxiety, and individual differences in determining how much risk is acceptable relative to health-related behaviors may all be key and reasonable components of individual decision making not captured by focusing only on the appropriateness of screening from a population perspective.

The approach to allow informed decision making driven by absolute numbers noting harms and benefits will hopefully be an improvement over our past failures to reach the medically underserved. There is nothing inherent in the approach to provide simple transparent information to patients that would exacerbate our long-standing problem of health disparities. We have failed to address issues in health disparities by not providing adequate education and information on cancer and cancer screening to all segments of our population. Recent trends in presentation of absolute, rather than relative, rates of harms and benefits are arguably a step forward in beginning to resolve this issue and advance toward truly informed decision making.

It is important to note that the needed shift to educating the public is not meant to add complexity to the process but rather

truth and clarity. What I am proposing is not a nuanced individualized approach to cancer screening, but rather the development of informational resources that can be provided to patients, with or without minimal guidance, for them to review. This might involve the development of simple one-page balance sheets or brief texts that frame the trade-off of harms and benefits in absolute terms (14,38). Such resources, considering differing levels of health literacy among consumers, should serve to simplify the decision-making process.

Conclusions

Professional medical groups and patient advocacy organizations have spent much time developing, debating, and promoting their worldviews for appropriate cancer screening guidelines. If we agree on the premise that individuals are supposed to be informed before making medical decisions, including decisions about cancer screening, then the time and talent of such groups could be much better spent educating the public on the harms and benefits of cancer screening. We have too often ignored the fact that people have different values related to false positives, false negatives, overdiagnosis, and perhaps most critically, overtreatment. We have focused on persuading rather than educating, implying that there is an a priori best choice for each individual.

To echo the message of others (39), it is easy to "sell" screening: just magnify the benefit, minimize the cost, and keep the numbers less than transparent. Screening can be very beneficial (or not), and screening messages should reflect the complexity of this decision. Reasonable people may disagree over the benefit of any given screening strategy, and a decision not to pursue screening may be just as reasonable as one to pursue. It is time for cancer control scientists, organizations, and advocacy groups to work together to develop an approach to screening that embraces, encourages, and routinely provides both the harms and benefits of cancer screening tests to all patients in a transparent fashion. It involves a fundamental respect for individuals and a tolerance for truly informed decisions even if, as individuals ourselves, we would not make the same choice.

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